UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUREPAC PHARMACEUTICAL CO.	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
TOMMY G. THOMPSON,	)	
Secretary of Health & Human Services,	)	
and LESTER M. CRAWFORD, JR.,	)	**Civil Action No. 02-1657 (ESH)**
Deputy Commissioner of Food and Drugs,	)	
	)	
Defendants,	)	
	)	
and	)	
	)	
APOTEX, INC., and TORPHARM, INC.,	)	
	)	
Intervenors-Defendants	)	
	)	

MEMORANDUM OPINION

This case arises out of the Food and Drug Administration's ("FDA" or "the agency") denial of Abbreviated New Drug Applications for generic formulations of the drug gabapentin submitted by plaintiff Purepac Pharmaceutical Co. ("Purepac"). The agency denied plaintiff's ANDAs because those applications failed to include the proper certification (a "paragraph IV certification") regarding a method of use patent covering gabapentin owed by the Warner-Lambert Company ("Warner-Lambert"). Purepac has now moved for a preliminary injunction requiring the FDA to accept the alternative statement (a "section viii statement") that the company filed regarding that patent and, accordingly, to approve its application to market a generic version of gabapentin for the treatment of

epilepsy. Plaintiff also requests that the agency be enjoined from approving any other gabapentin ANDAs for that same use, including an application filed by defendants-intervenors TorPharm, Inc. and Apotex Corp. ("TorPharm").

On December 6, 2002, pursuant to FED. R. CIV. P. 65(a)(2), the Court informed the parties of its decision to consolidate the preliminary injunction motion with a final decision on the merits. Plaintiff's motion will therefore be treated as a motion for summary judgment. Moreover, on December 12, 2002, in response to the Court's decision to consolidate, TorPharm submitted a motion for summary judgment asserting that plaintiff's claims for declaratory and injunctive relief are barred by the doctrine of laches. Plaintiff responded to this motion on December 13, 2002, the same day that the parties presented oral argument in this case.[1/] Based on the pleadings and on the arguments of counsel, and for the reasons given below, the Court will enter judgment on behalf of plaintiff, deny TorPharm's motion for summary judgment, and order the FDA to accept Purepac's section viii statement. However, the Court will not enjoin the FDA from approving TorPharm's application, but will instead leave this decision to the agency in the first instance.

BACKGROUND

I. Statutory and Regulatory Framework

[1/] In this response, plaintiff also voluntarily withdrew, without prejudice, the fourth claim for relief asserted in its complaint, which had not been addressed in its preliminary injunction papers. Accordingly, the Court's decision on the remaining claims will constitute a final, immediately appealable decision.

At issue in this case are the complex set of amendments to the Food, Drug, and Cosmetic Act ("FDCA") added by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984), *codified at* 21 U.S.C. § 355. These amendments were designed to simplify and expedite the process by which generic drugs are brought to market. Generally, a company seeking FDA approval to market a particular drug must file a lengthy document called a New Drug Application ("NDA"), which, among other things, must include detailed data establishing the drug's safety and effectiveness. The NDA must also contain information on each patent that claims the drug or a method of using the drug that is the subject of the application and with respect to which a patent infringement claim could reasonably be asserted against a unauthorized party. 21 U.S.C. § 355(b)(1); (c)(2).[2/] The FDA publishes the patent information that it receives in a publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," known in agency parlance as the "Orange Book." *See Am. Bioscience, Inc. v. FDA*, 269 F.3d 1077, 1079 (D.C. Cir. 2001); Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD & DRUG L.J. 245, 249-50 (1999).

Before the Hatch-Waxman Amendments were enacted, a firm that hoped to manufacture and sell a generic version of an already-approved drug was required to submit a new NDA complete with new safety and effectiveness data. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). Obviously, this requirement imposed considerable burdens on would-be generic

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[2/] By regulation, the FDA has defined the three types of patents that may be submitted in conjunction with a NDA: drug substance (active ingredient patents); drug product (formulation and composition) patents; and method of use patents. *See* 21 C.F.R. § 314.53(b).

manufacturers, delaying and increasing the cost of bringing generic drugs to market. In order to benefit consumers, the amendments altered this requirement, creating a streamlined procedure for the approval of generic drugs whereby the generic applicant is permitted to piggyback on the original NDA filed by the manufacturer of the brand-name drug (the so-called "pioneer" or "innovator" drug). Under this new system, generic drugs may be approved through an Abbreviated New Drug Application ("ANDA"), which relies on the FDA's previous determination that the pioneer drug is safe and effective. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 675 (1990) ("The ANDA applicant can substitute bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full new drug application."). This allows applicants to avoid the costly and time-consuming process associated with NDAs, thus facilitating the approval and dissemination of low-costs generic drugs. *See* H.R. Rep. No. 98-857 (Part I) at 14 (June 21, 1984).

At the same time, Congress sought to protect patent holders whose rights could be threatened by the marketing of generic versions of their patented innovations. *See Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 580 (D.C. Cir. 2001). To this end, the Hatch-Waxman Amendments require that ANDAs contain specified information about the patents protecting the pioneer drug, including "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). There are two means by which applicants may satisfy this requirement; this case turns on the difference between the two

approaches and a determination as to whether the FDA properly rejected plaintiff's use of one instead of the other.

First, in a situation in which the patent potentially implicated by the generic drug "claims the listed [*i.e.* FDA-approved[3/]] drug . . . or which claims a use for such listed drug for which the applicant is seeking approval," the ANDA applicant is required to certify that the new drug will not infringe the patent and explain why it will not. 21 U.S.C. § 355(j)(2)(A)(vii). The statute provides four bases on which this certification may be made: (I) that the required patent information has not been filed; (II) that the patent has expired; (III) that the patent will expire on a date certain; or (IV) that the patent is invalid or will not be infringed by the drug for which approval is sought. *Id*. Because the fourth option – called a "paragraph IV certification" – is the most complicated and the only one at issue in this case, it demands further explanation.

When an ANDA includes a paragraph IV certification, the applicant must give notice of the filing both to the owner of the patent and to the holder of the NDA for the approved drug. The statute then provides a 45-day window during which the patent owner may bring suit against the generic applicant.[4/] If a suit is initiated, the FDA's approval of the ANDA is automatically stayed for 30

[3/] *See* 21 C.F.R. 314.3(b) ("Listed drug means a new drug product that has an effective approval under section 505(c) of the act for safety and effectiveness or under section 505(j) of the act, which has not been withdrawn or suspended under section 505(e)(1) through (e)(5) or (j)(5) of the act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness.").

[4/] 35 U.S.C. § 271(e)(2)(A) makes it an act of infringement to submit an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." Thus, whenever a generic applicant includes a paragraph IV certification in its ANDA, this provision creates a "somehwat artificial" case or controversy for purposes of establishing federal jurisdiction and permits the brand manufacturer to initiate a patent infringement suit even though the generic manufacturer has not yet marketed the drug. *See Eli Lilly*, 496 U.S. at 676; *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir.

months, a period that can be lengthened or shorted by the court hearing the case if either party fails to "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii). If, before the expiration of the 30-month stay, the court finds that the patent is invalid or would not be infringed by the new drug, the FDA's approval of the ANDA becomes effective on the date of that ruling. *See Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001). As an incentive to generic manufacturers willing to run the risk of defending against patent infringement actions, the statute provides that the first party to gain approval of an ANDA containing a paragraph IV certification is entitled to a 180-day period of market exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). During this "[e]denic moment of freedom from the pressures of the market," *Mova Pharm.*, 140 F.3d at 1064, the FDA may not allow any subsequent ANDAs for the drug in question to become effective, thus allowing the first mover to sell its drug without competition from other generic manufacturers. *See Mylan Pharm., Inc. v. Shalala*, 81 F. Supp.2d 30, 33 (D.D.C. 2000) ("In other words, no ANDA for the same generic drug product will be approved during those 180 days.").

As noted, however, the statute provides an alternative to a paragraph IV certification, known as a "section viii statement," which applies where the patent in question is a "method of use patent which *does not claim a use* for which the applicant is seeking approval under this subsection." 21 U.S.C. § 355(j)(2)(A)(viii) (emphasis added). By regulation, the FDA has provided that these statements are to be used when "the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent" that has been submitted

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1997).

by the NDA holder. 21 C.F.R. § 314.94(b)(12)(iii)(A). In such circumstances, the ANDA applicant need not file a patent certification under paragraphs I-IV; instead, the ANDA must include a statement that the method of use patent at issue does not claim the use of the drug for which the applicant is seeking approval. *Id*; *see also Mylan Pharm., Inc. v. Thompson*, 139 F. Supp.2d 1, 6 (D.D.C. 2001), *rev'd on other grounds*, 268 F.3d 1323 (Fed. Cir. 2001). An applicant proceeding by means of a section viii statement need not inform the patent owner of its application, and does not face an infringement action under 35 U.S.C. § 271(e)(2)(A) (*see supra* note 4) or the automatic 30-month stay applicable to paragraph IV certifications should the owner decide to file an infringement action. Thus, the FDA may approve a section viii application immediately, making it an attractive route for generic manufacturers, even though a section viii statement does not entitle a successful applicant to the 180-day period of exclusivity bestowed on paragraph IV applicants.

As the above description makes clear, the availability of section viii statements turns on whether the method of use patent covering the pioneer drug actually "claims" the use for which the ANDA applicant seeks to market the generic version of that drug. To understand how this works requires a more detailed examination of the process by which patents claiming certain uses for drug products come to be registered with the FDA. As already described, every NDA must contain patent information regarding the drug for which the applicant seeks approval. 21 U.S.C. § 355(b)(1). By regulation promulgated on October 3, 1994, however, the FDA added a caveat to this statutory mandate: "For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." 21 C.F.R. § 314.53(b). Once the NDA is approved, the applicant then has 30 days in which to amend its

patent submissions to ensure that they list only those patents "that claim[] the formulation, composition, or the specific indications or other conditions of use that have been approved." 21 C.F.R. § 314.53(c)(2)(ii). If a patent for an approved drug is obtained after the NDA has been accepted, the owner must list the new patent information within 30 days after the patent is issued. 21 U.S.C. § 355(c)(2). The FDA lists all of these patent submissions in the Orange Book.

Two points about the Orange Book are especially important. The first is the FDA's insistence that method of use patents can be listed and remain in the book *only* if such patents actually claim a use that has been approved by the agency. Thus, a patent that claims an unapproved method of using an approved drug should not be submitted, and if such a listing appears in the Orange Book, the holder of the NDA is obliged to submit information to correct the error. These are not statutory requirements, but rather have been imposed by regulation. *See* 21 C.F.R. § 314.53(b); Proposed Rules, Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,908 (July 10, 1989) (hereinafter "Proposed ANDA Rules") ("[I]nformation will be published in the list only on patents that claim approved drug products or that claim approved indications or other conditions of use.").

Second, the FDA does not take it upon itself to review the patent submissions it receives from NDA applicants and holders in order to determine whether they actually relate to approved drugs and uses. Instead, the agency views of its role as purely ministerial. Lacking the resources or the expertise to determine the validity or scope of patent claims, the FDA simply lists the patent information that it receives from brand manufacturers, expecting those parties to understand and abide by the regulatory mandates. *See* Abbreviated New Drug Application Regulations, Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,345 (Oct. 3, 1994) (hereinafter "ANDA Rulemaking"); Mahn, *supra*, at 250

(noting the FDA's "willingness to list in the Orange Book virtually any patent submitted by an NDA holder").

Indeed, in formulating its regulations governing patent submissions, the FDA explicitly declined to establish "a mechanism for review of submitted patent information to determine, at least on a very general basis, applicability to the particular NDA in question." *ANDA Rulemaking*, 59 Fed. Reg. at 50,343; *see aaiPharm Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002) (upholding the FDA's "purely ministerial approach to the Orange Book listing process" as a reasonable interpretation of its statutory responsibilities). The duty to ensure that the Orange Book only lists patents that actually claim approved drugs thus lies with NDA holders. *See Watson Pharm., Inc. v. Henney*, 194 F. Supp.2d 442, 445-46 (D. Md. 2001) ("In making its decision to list a patent . . . it is entirely appropriate and reasonable for the FDA to rely on the patentee's declaration as to coverage, and to let the patent infringement issues play out in other, proper arenas, as is the clear intent of the Hatch-Waxman Amendments.").

Despite the FDA's hands-off approach, its rules do provide an internal procedure whereby parties – including ANDA applicants – can dispute the accuracy or relevance of patent information listed in the Orange Book. That party must first notify the agency of its basis for disagreeing with the listing. The agency will then request that the NDA holder confirm the correctness of the patent information. However, unless that application holder "withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list." 21 C.F.R. § 314.53(f). If the holder of the NDA does not do so, any ANDA application "submitted for a drug that is claimed by a patent for which information has been submitted must, despite any disagreement as to

the correctness of the patent information, contain an appropriate certification for each listed patent." *Id.*; *Am. Bioscience*, 269 F.3d at 1080; *see also aaiPharma*, 296 F.3d at 237 ("In short, FDA's position is that if the NDA holder stands on its Orange Book listing, aggrieved parties are out of luck."). The FDA has concluded that such disputes about the scope of particular patents are best resolved by private litigation between the pioneer manufacturer and the generic applicant, rather than by agency action. *See ANDA Rulemaking*, 59 Fed. Reg. at 50,348.[5/]

II. Factual Background

A. *New Drug Applications for Gabapentin*

The drug product at issue is gabapentin, which is currently marketed by Warner-Lambert (now a division of Pfizer, Inc.) under the brand name Neurontin®. Until mid-2002, the only FDA-approved use for gabapentin was for the treatment of epilepsy.[6/] The FDA approved Warner-Lambert's NDAs for gabapentin in December 1993 (capsule form) and October 1998 (tablet form). In connection with these applications, Warner-Lambert submitted information to the agency on a variety of patents connected with the drug. Of these, two were method of use patents and are thus important to the

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[5/] It has been held, however, that a generic drug manufacturer has no cause of action under either the Hatch-Waxman Amendments or the patent laws to obtain declaratory or injunctive relief requiring an NDA holder to "delist" a patent improperly listed in the Orange Book. *See Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001); *cf. Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1378-79 (Fed. Cir. 2002) (affirming *Mylan*, but suggesting that a generic manufacturer could bring an APA challenge against the FDA based on the agency's failure to inquire into the correctness of an Orange Book listing).

[6/] In 2002 the agency approved gabapentin for postherpetic neuralgia, a use that is protected by a three-year non-patent market exclusivity conferred by a separate provision of the Hatch-Waxman Amendments, and is not relevant to this case. (Pl.'s Mot. for Prelim. Inj. at 11 n.11.)

Court's analysis.[7/] First, U.S. Patent No. 4,087,544 ("the '544 patent") claims a method of using gabapentin to treat epilepsy. This patent expired on July 16, 2000. The second, and in this litigation, more important patent is U.S. Patent No. 4,084,479 ("the '479 patent"), which is not set to expire until January 2010. Determining the use claimed by the '479 patent is at the heart of this case.

When Warner-Lambert submitted its NDA for the tablet form of gabapentin in July 1997, it submitted a declaration stating that the '479 patent "claims a method for treating neurodegenerative diseases." (Administrative Record ["A.R."], tab 11.) However, the declaration also stated that the '479 patent, along with the'544 patent and the '476 patent, "cover a crystal form and *the use* of Neurontin (gabapentin)." (*Id*. (emphasis added)) Then, by letter dated November 16, 1998, which responded to the FDA's request to provide patent information for publication in the Orange Book, Warner-Lambert confirmed its earlier statements. (A.R., tab 13.) Once again, the company described the '479 patent as use patent "to treat neurodegenerative diseases." And again, Warner-Lambert declared that the '479 patent, the '544 patent, and the '476 patent together "cover the composition, formulation and/or method of use of Neurontin®." (*Id.*) In April 2000 Warner-Lambert made virtually identical declarations about the '479 patent in the process of submitting information to the FDA about the '482 patent.[8/] (A.R., tab 22.)

[7/] The other patent information submitted by Warner-Lambert related to a drug substance patent, U.S. Patent No. 4,894,476 ("the '476 patent"), and a composition patent, U.S. Patent No. 6,054,482 ("the '482 patent"), neither of which are relevant to this case.

[8/] Apparently, Warner-Lambert made similar declarations in connection with its NDA for the tablet form of gabapentin, which the FDA approved in 1993. At that time, the FDA regulations mandating that only patents covering approved uses may be submitted in connection with NDAs had not yet gone into effect. However, these declarations have not been included in the Administrative Record for this case, and do not impact the Court's decision. Moreover, as set forth above, Warner-Lambert's declarations remained consistent after the 1994 effective date of the regulations, so it is immaterial what

Based on these submissions, the FDA listed the '479 patent, along with the '476, '482, and '544, patents, in the Orange Book. (A.R., tab 39.)[9/] When it did so, the agency also created "use codes" for the two method of use patents. These codes allow interested parties, including ANDA applicants, to determine the particular medical uses of brand-name drugs asserted by the various use patents listed in the Orange Book. *See ANDA Rulemaking***,** 59 Fed. Reg. at 50,346 ("In addition, for a use patent, FDA includes in the Orange Book a code identifying the indication covered by the patent."). The code assigned to the '544 patent was U-106, "treatment for epilepsy." The agency created a separate code for the '479 patent, U-258, "treatment of neurodegenerative diseases," which mirrors Warner-Lambert's statements about the scope of that patent.[10/] (A.R., tab 39.)

B. *Abbreviated New Drug Applications for Gabapentin*

In March 1998 and September 1999, Purepac filed ANDAs with the FDA seeking approval to market generic versions of gapapentin capsules and tablets, respectively, for the treatment of epilepsy. (A.R., tabs 8-9.) The company did not request, and has not requested, the right to market gabapentin for the treatment of neurodegenerative diseases, a use for which the drug has never been approved by

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Warner-Lambert said in its declaration in 1993.

[9/] When the '544 patent expired on July 16, 2000, it was removed from the Orange Book. The '479 patent, however, remains listed, along with the '476 and '482 patents.

[10/] At oral argument, the FDA explained that in assigning use codes it relies exclusively on the NDA holder's statements regarding a patent's coverage. In other words, the agency does not make an independent effort to construe the patents in question. Here, there is no indication that Warner-Lambert specifically asked that any particular code be assigned to either of its method of use patents. Apparently, then, the FDA simply followed the company's representations that the '479 patent claimed the use of treating neurodegenerative diseases and that the '544 patent claimed the use of treating epilepsy in order to generate those respective use codes.

the FDA (also referred to as an "off-label" use). Indeed, because epilepsy was the only indication for which that drug had been approved at the time its ANDAs were submitted, Purepac could have asked for no more.

As required by the Hatch-Waxman Amendments, Purepac submitted patent declarations along with its ANDAs. With respect to the '544 patent, Purepac offered a paragraph III certification stating that the patent would expire on July 16, 2000. With respect to the '476 patent (and ultimately, in May 2000, the '482 patent), the company provided paragraph IV certifications that these patents were invalid and/or would not be infringed by its generic version of gabapentin. (A.R., tabs 23, 24, 36.) The FDA took no issue with these certifications. In contrast, as to the '479 patent, Purepac submitted a section viii statement. (*Id*.) Explaining its use of this mechanism, Purepac asserted – based on Warner-Lambert's submissions and the use code assigned by the FDA – that the '479 patent claimed the use of the drug to treat neurodegenerative diseases. Because the ANDA was seeking approval only to treat epilepsy, the company concluded that a section viii statement was appropriate.

Purepac defended this decision in a letter to the FDA on March 5, 1999. It contended that a section viii statement was proper (and a paragraph IV certification improper) because "the '479 patent is a method of use patent covering an indication which is not present in the innovator's approved labeling." (A.R., tab 5, attach. 1.) The FDA responded on March 23, 1999, announcing that "[i]t is not the responsibility of the Agency to correct patent information," and informing Purepac of its right to use 21 C.F.R. § 314.53(f) to challenge Warner-Lambert's submission of the '479 patent for inclusion in the Orange Book. (A.R., tab 5, attach. 2.) The dispute, as the agency understood it, was between Purepac and Warner-Lambert, and was not susceptible to

FDA resolution. In its letter, the agency also relayed that it had informally consulted with Warner-Lambert's patent attorney, who confirmed the accuracy of the listing. In light of that dispute, the agency reported that it was unable to confirm that Purepac had properly used a section viii statement with respect to the '479 patent.[11/] (*Id*.)

The FDA elaborated on its position in letters to Purepac dated April 25, 2002 (with respect to the ANDA for capsules) and July 29, 2002 (with respect to the ANDA for tablets), which advised that a section viii statement was inappropriate for the '479 patent, and that in order to secure agency approval, Purepac should submit a revised certification for that patent under either paragraph III or IV. (A.R., tabs 8-9.) The agency supported this conclusion by relying on an April 8, 2002 letter it had sent to Purepac.[12/] In that letter, the FDA explained why the '479 patent was not the proper subject of a section viii statement:

> A section viii statement is appropriate when – and only when – generic drug labeling is "carved out" (omits an indication or protected labeling) to avoid infringement of a listed patent. This approach permits approval of ANDAs as appropriate when some of an innovator's market protections have expired, while protecting the paragraph IV certification process for resolving patent disputes. . . . Purepac is not proposing to omit information related to the approved use from the generic gabapentin labeling. It is seeking approval for the same indication approved for Neurontin®. Warner-Lambert has submitted the '479 patent as claiming the approved use for Neurontin®. Although Purepac believes this patent does not correspond to the approved labeling, Warner-Lambert has submitted an adequate declaration stating that it does. If Purepac disagrees with Warner-Lambert about whether the use patent claims the labeling for

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[11/] Despite the FDA's suggestions, Purepac never invoked § 314.53(f) to challenge Warner-Lambert's listing of the '479 patent in the Orange Book. At oral argument, Purepac explained that it did not follow the FDA's suggestion because it had no dispute over Warner-Lambert's listing since neither company treated the'479 patent as claiming the use of treating epilepsy.

[12/] This letter responded to a letter written by Purepac to the agency on December 14, 2001, in which the company reiterated its position that the '479 claims a method of using gabapentin for the treatment of neurodegenerative diseases and that because this was an unapproved (or off-label) use of the drug, a paragraph IV certification for that patent would have been inappropriate. (A.R., tab 4.)

> which Purepac now seeks approval, the appropriate course is to submit a paragraph IV certification and, if sued for patent infringement, resolve the issue in court.

(A.R., tab 1.) In other words, because the only use for which gabapentin has been approved by the FDA is the treatment of epilepsy, any method of use patent submitted by Warner-Lambert for inclusion in the Orange Book must have claimed that approved use. Therefore, according to the agency, a section viii statement was inappropriate because the use for which Purepac sought approval was the same as the use that must have been claimed by the patent in question.

This disapproval of Purepac's application is complicated by the fact that another would-be generic manufacturer, defendant-intervenor TorPharm (through its American affiliate Apotex), had already submitted an ANDA for the same use of gabapentin that included a paragraph IV certification regarding the '479 and '476 patents. Though TorPharm filed its ANDA to market a generic verison of gabapentin capsules several weeks after Purepac (on April 17, 1998), it was the first to supply a paragraph IV certification as to the '479 patent.[13/] TorPharm amended its ANDA to include a paragraph IV certification with respect to the '482 patent on June 13, 2000, a month after Purepac had done the same.

The filing of these paragraph IV certifications triggered Warner-Lambert's patent infringement action against TorPharm, which was filed on July 14, 1998. On March 2, 2001 and September 14, 2001 respectively, the U.S. District Court for the Northern District of Illinois granted summary

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[13/] Actually, with respect to the '479 patent, TorPharm's application contained *both* a paragraph IV certification and a section viii statement. (A.R., tab 27.) According to defendants, the FDA simply disregarded TorPharm's section viii statement. (Def.'s Opp. at 11.) At oral argument, TorPharm explained that it submitted a paragraph IV certification and a section viii statement because there was a confusion as to which of these alternatives was appropriate.

judgment in favor of TorPharm with respect to both the '476 and '479 patents. *See Warner-Lambert Co. v. Apotex Corp*., 2001 WL 1104618 (N.D. Ill. Sept. 14, 2001). Warner-Lambert has appealed the decision on the '479 patent (but not the '476 patent) to the Federal Circuit, which has heard argument but has not yet rendered a decision. The issue in that case concerns not the scope of the '479 patent (*i.e*. whether it covers the treatment of epilepsy), but instead whether TorPharm's generic version of gabapentin is likely to induce infringement of the '479 patent by being used for the off-label (and infringing) purpose of treating neurodegenerative diseases.[14/] *See id*. at *2. More recently, on July 20, 2000, Warner-Lambert again sued TorPharm in the Northern District of Illinois, this time for infringement of the '482 patent. Like its predecessors, that suit triggered a 30-month stay on the FDA's approval of TorPharm's ANDA, a stay set to expire on December 15 of this year.[15/]

Concerned that the agency would approve TorPharm's ANDA as soon as that stay was lifted, Purepac brought the present action on August 20, 2002. After the FDA refused plaintiff's request to abstain from taking action regarding that application on December 15, Purepac filed a motion for a

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[14/] In two separate actions filed in New Jersey on June 11, 1998 and December 2, 1999, respectively, Warner-Lambert appears, inexplicably, to have sued Purepac for infringing the '479 patent under 35 U.S.C. § 271(e)(2)(A), even though the company's section viii statement prevented Warner-Lambert from obtaining an automatic 30-month stay on Purepac's ANDAs. In the same actions, however, Warner-Lambert alleged infringement of the '476 patent (for which Purepac also filed a paragraph IV certification), which did trigger a 30-month stay. (Rakoczy Dec., attachs. A & B.) While the New Jersey court has not yet decided these cases, the stay based on this litigation has long since expired.

[15/] As noted, Purepac also filed a paragraph IV certification regarding the '482 patent. On that basis, Warner-Lambert also brought an infringement action against Purepac on July 20, 2000. The corresponding 30-month stay of Purepac's ANDA is set to expire on January 20, 2003. (Def.'s Opp. at 12 & n.5.).

preliminary injunction on November 13, which the Court agreed to decide by December 16.[16/] Subsequently, the Court invoked Rule 65(a)(2) to consolidate the preliminary injunction hearing with a final decision on the merits. As such, plaintiff's motion papers will be treated as a motion for summary judgment, and the analysis that follows focuses only on the merits of Purepac's claim that the FDA violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 701, *et seq*., by failing to approve its ANDAs because they contained section viii statements regarding the '479 patent instead of paragraph IV certifications. However, before addressing this issue, the Court must first consider whether Purepac's claims for declaratory and injunctive are barred, as TorPharm argues, by the doctrine of laches.

ANALYSIS

I. TorPharm's Laches Defense

Laches is an equitable doctrine, designed to serve the maxim that "equity aids the vigilant, not those who slumber on their rights." By preventing the enforcement of stale claims, the doctrine obliges litigants to pursue their rights expeditiously. *See N.A.A.C.P. v. N.A.A.C.P. Legal Def. & Educ. Fund, Inc.*, 753 F.2d 131, 137 (D.C. Cir. 1985); *Gull Airborne Instruments, Inc. v. Weinberger*, 694 F.2d 838, 843 (D.C. Cir. 1982). This Circuit has identified two preconditions for any laches defense: "a claim will not be barred under that doctrine unless it is shown that the party raising the

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[16/] The FDA suggested that, absent a court decision to the contrary, it is likely to approve TorPharm's ANDA as soon as the stay is lifted. Such approval would allow TorPharm to market generic gabapentin immediately, and with a de facto exclusivity, as no action can be taken on Purepac's rival applications until at least January 20, 2003. However, to allow the Court sufficient time to render this decision, the agency agreed not to approve TorPharm's ANDA until the end of the day on December 16, 2002.

defense was prejudiced by the other party's delay in raising the claim and that the delay was unreasonable." *Burka v. Aetna Life Ins. Co.*, 56 F.3d 1509, 1514 (D.C. Cir. 1995). Therefore, in deciding whether to apply the doctrine here, the Court must consider (1) whether plaintiff inexcusably or unreasonably delayed filing this suit; and (2) whether TorPharm was prejudiced because of that delay. *See Nat'l Wildlife Fed'n v. Burford*, 835 F.2d 305, 318 (D.C. Cir. 1987); *Minkoff v. Clark Transfer, Inc*., 841 F. Supp. 424, 429 (D.D.C. 1993).

Because TorPharm cannot meet its burden of demonstrating either element, plaintiff's claims are not barred by laches. As to the first prong, TorPharm argues that Purepac could and should have brought suit against the FDA immediately after receiving the agency's March 23, 1999 letter, which TorPharm believes constitutes final agency action. This, however, is far from clear. (Intervenors-Def.s Mot. for Summ. J. at 5.) While it ostensibly addresses Purepac's contention that TorPharm's paragraph IV certification regarding the '479 patent should be rejected, the letter's only response is to point Purepac to the FDA's regulatory provisions for contesting Orange Book listings that may be erroneous. (A.R., tab 5, attach. 2.) Significantly, the letter does not tell Purepac that its ANDAs will not be approved with section viii statements, nor does it direct the company to amend its applications to include paragraph IV certifications.

As such, the FDA does not appear to have imposed any actual legal obligation on Purepac, nor does it conclusively determine any of the company's rights or duties regarding its generic applications. These, however, are the necessary tokens of final agency action. *See AT&T v. EEOC*, 270 F.3d 973, 975 (D.C. Cir. 2001) ("An agency action is deemed final if it marks the consummation of the agency's decisionmaking process and determines rights or obligations. The agency must have made up its mind,

and its decision must have inflicted an actual, concrete injury upon the party seeking judicial review.") (internal citations and quotation marks omitted). And, in their absence, it was reasonable for Purepac to refrain from bringing suit to challenge the FDA's letter.

Moreover, in March 1999, Purepac's ANDAs were in the throes of a 30-month stay resulting from Warner-Lambert's infringement action as to the '476 patent. (Pl.'s Reply at 18.) This stay was not set to expire until July 2001. Purepac was therefore not in a position to suffer any actual hardship as a result of the agency's letter until at least that time. Under these circumstances, with over two years remaining before the challenged agency action could have inflicted any tangible injury, the company could have reasonably believed that an immediate suit would have been subject to a successful ripeness or standing defense. *See, e.g.*, *Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999) (holding that the FDA's approval of an ANDA was not ripe for adjudication where that approval was conditioned on the expiration of a 30-month stay that still had months to go).

For these reasons, the Court rejects TorPharm's claim that the clock on Purepac's exercise of its rights started to run in March 1999. Instead, it was not until after the FDA issued its April 8, 2002 letter that it would have been reasonable for plaintiff to bring the instant action. For, unlike the agency's prior letter, this document specifically addressed the circumstances under which section viii statements were appropriate and clearly instructed Purepac that its ANDAs would not be eligible for final approval until the company amended those applications to include paragraph IV certifications. (A.R., tab 1 ("Therefore, to be eligible for final approval, Purepac must submit an amended patent certification to its pending ANDA for gabapentin.").) This letter was far more definite and more explicit in its

prescriptions than the agency's March 1999 letter, and therefore – unlike its predecessor – it bears the hallmarks of final agency action.

However, while Purepac could have brought suit to challenge the legality of the agency decision expressed in this new document soon after it issued, the Court cannot conclude that the company's decision to wait less than five months to do so was unreasonable. Indeed, it is not at all apparent how or why plaintiff's claims could have became significantly more stale between early April and mid-August, when Purepac at last brought suit. Moreover, and more importantly, there is no evidence whatsoever that TorPharm was prejudiced *by virtue of* Purepac's relatively brief delay in filing suit. Thus, while TorPharm spends the bulk of its motion arguing about the money and market share that it will lose should Purepac prevail in its challenge to the FDA's action (Intervenor-Def.'s Mot. for Summ. J., at 15-17), this is simply not the proper inquiry for purposes of evaluating a laches challenge.

Instead, the question is whether TorPharm was harmed because Purepac failed to assert its challenge soon enough. The case law makes clear that the party asserting a laches defense must have relied on the plaintiff's inaction, and must have been harmed on account of that reliance. *See NAACP*, 753 F.2d at 138-39 & n.75 (holding that "mere passage of time does not bar injunctive relief," but that prejudice could result from "the loss of the investment in labor and capital *in reliance upon the plaintiff's inaction*") (emphasis added); *Mahan v. Tash*, 703 F. Supp. 130, 132 (D.D.C. 1989) (laches applicable where "*by reason of his delay* the adverse party has good reason to believe that the alleged rights are worthless, or have been abandoned" (quoting *Am. Univ. Park Citizen's Ass'n v. Burka*, 400 A.2d 737, 742 (D.C. 1979)) (emphasis added). TorPharm is unable to pass this test.

In an effort to do so, the company focuses both on its decision to litigate Warner-Lambert's suits on the '476 and '479 patents, and on the considerable amount of money that it has invested to

prepare for a commercial launch of generic gabapentin, money that it would probably be unable to recoup if Purepac's suit succeeds. However, in light of the Court's conclusion that Purepac's alleged "delay" could only have begun in April 2002, the first point is irrelevant. By that time, the '476 and '479 infringement suits had already been fully litigated and decided in the district court, and it is not reasonable to expect that TorPharm would have abandoned the case on appeal even if Purepac had brought this suit somewhat sooner.

As for TorPharm's capital expenditures, the company has not demonstrated that its decision to prepare for an instantaneous product launch as soon as its ANDA is approved on December 16 was in any way tied to Purepac's five-month hesitation in filing the instant action. Indeed, TorPharm has presented no evidence as to *when* it spent the millions that it did to stock the drug. The Court thus has no way of knowing whether TorPharm made its investments before or after April 2002. Without such a showing, there is simply no basis for determining that TorPharm acted in reliance on Purepac's delay. The Court therefore cannot conclude that had Purepac filed immediately after receiving the FDA's April 8 letter, TorPharm would not have invested as it did.

Nor is it plausible to believe that TorPharm, which has made its considerable gabapentin investments despite considerable uncertainty and risk well beyond the outcome of this suit,[17/] would have retreated from those investments if Purepac had filed this suit a few months earlier. Moreover, the suggestion that had Purepac done so, this matter could have been resolved before those investments

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[17/] In addition to the possibility that the Federal Circuit could reverse the district court's decision that TorPharm's generic gabapentin product does not infringe the '479 patent, TorPharm faces the not insignificant risk of more litigation from Warner-Lambert should it begin to market that product before any judicial resolution of the infringement claims regarding the '482 patent, which are still pending in the District Court of New Jersey.

were finalized is highly dubious given the unusually expedited track on which this case has been adjudicated. As such, TorPharm would have been in exactly the same situation as it is now. TorPharm has therefore fallen short of establishing that it suffered any prejudice as a result of Purepac's (not unreasonable) delay in pursuing this challenge to the FDA decision embodied in the agency's April 2002 letter. Because there is no merit to TorPharm's laches defense, the Court will now proceed to the merits of plaintiff's case.

II. Purepac's APA Claim

Evaluating the FDA's decision to reject Purepac's ANDAs must begin with the text of the FDCA. And, while the legal and factual background to this case may be complex, there is actually little disagreement among the parties about the meaning of the applicable statutory provision. As the agency acknowledges, "FDA agrees with Purepac that a section viii statement must be submitted when an ANDA applicant does not seek approval for a use claimed by the patent at issue." (Def.'s Opp. at 26.) This agreement is not surprising, as the language of section viii is quite clear: a statement of inapplicable use under section viii is required with respect to "a method of use patent which does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(2)(A)(viii).[18/] Here, of course, there is no dispute that Purepac's ANDAs sought approval to use gabapentin for the treatment of epilepsy. Accordingly, the legality of the FDA's refusal to approve those applications because they included section viii statements rises or falls solely on the agency's conclusion that the '479 patent

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[18/] As described above, the FDA's regulation interpreting this provision is equally clear. The regulation states that a section viii statement is to be used whenever "the labeling for the drug product for which the applicant is seeking approval does not include any indications that are *covered* by the use patent." 21 C.F.R. § 314.94(b)(12)(iii)(A) (emphasis added).

"claims" the use of treating epilepsy. Because the Court can find no rational basis for that conclusion, the agency's decision cannot stand.

Before explaining this conclusion, the Court must first address the policy arguments raised by the FDA. The agency insists that this case is about "whose characterization of the patent controls," *i.e.*, whether the patent owner or the generic applicant is the appropriate party to determine what uses are claimed by a patent. (Def.'s Opp. 26.) It is important in this respect to remember that while the FDA requires NDA applicants to submit information about their method of use patents, the agency has disclaimed any role in determining what uses a particular patent claims. *See Patent Provisions Rulemaking*, 59 Fed. Reg. at 50,345 ("FDA does not have the resources to review patent information for its accuracy and relevance to an NDA."); *Proposed ANDA Rules*, 54 Fed. Reg. at 28,909 ("Because the FDA has no experience in the field of patents, the agency has no basis for determining whether a use patent covers the use sought by the generic applicant.").

However, such agency self-abnegation creates the possibility for conflict between NDA holders and ANDA applicants over the proper scope of a particular use patent. For example, the former may submit information about a patent that the latter believes overstates the proper scope of the patent in question. In addressing these conflicts, the FDA has taken the position that the assessment of a patent's scope should be left in the hands of the NDA holder rather than the generic applicant.[19/] (Def.'s Opp. at 27-32.) This is true even if the patent information submitted by the former misrepresents or distorts the coverage of a use patent. For purposes of the ANDA, then, the applicant

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[19/] This regulatory position is not new. *See Proposed ANDA Rules*, 54 Fed. Reg. at 28,909 ("The agency believes that [this] approach more fairly implements Congress' intent that patent owners receive preapproval notice of potentially infringing patents.").

must accept the patent uses claimed by the pioneer. Therefore, if the applicant seeks approval for a use that the NDA holder has asserted (even incorrectly or disingenuously) that the patent claims, a section viii is improper. *See Proposed ANDA Rules*, 54 Fed. Reg. at 28,909. Instead, under those circumstances, a paragraph IV certification is required, which allows the true scope of the patent to be judicially determined in the context of the § 271(e)(2)(A) infringement action that is all but certain to follow. (Def.'s Opp. at 32 n.16.)

The Court takes no issue with this long-standing policy of deference to NDA holders' characterizations of the scope of use patents.[20/] However, in light of the unique factual circumstances presented here, this case does not implicate these policy concerns. Here, had the FDA actually deferred to the NDA holder's description of the '479 patent's coverage, it should have accepted Purepac's section viii statement regarding that patent. For, at every opportunity, Warner-Lambert consistently declared to the agency that the '479 patent "claims" the use of gabapentin to treat neurodegenerative diseases, not epilepsy, which of course is the only indication for which Purepac seeks approval.[21/]

[20/] Two recent decisions have specifically endorsed the FDA's approach. *See aaiPharm*, 296 F.3d at 241 ("[T]he whole point of the Act's paragraph IV certification scheme is to let private parties sort out their respective intellectual property rights through patent infringement suits while the FDA focuses on its primary task of ensuring that drugs are safe and effective. This division of labor is appropriate because the FDA has no expertise in making patent law judgments."); *Watson Pharm.*, 194 F. Supp.2d at 445 ("[The FDA] has no expertise – much less any statutory franchise – to determine matters of substantive patent law. In making its decision to list a patent, therefore, it is entirely appropriate and reasonable for the FDA to rely on the patentee's declaration as to coverage, and to let the patent infringement issues play out in other, proper arenas. . . ."). The Court's opinion in this case is entirely consistent with these decisions.

[21/] There is no dispute that epilepsy is *not* a neurodegenerative disease. Treating such diseases with gabapentin is therefore unquestionably a different use of that drug than is treating epilepsy, as Warner-Lambert itself has acknowledged. (Pl.'s Reply at 6 n.2.)

First, in 1993, Warner-Lambert submitted information about the '479 patent in connection with its NDA for gabapentin capsules. This declaration stated that "U.S. Patent No. 5,084,479 is owned by Warner-Lambert Company. It covers a method of treating neurodegenerative diseases with gabapentin." (A.R., tab14.) Then, in 1997, in connection with its NDA for gabapentin tablets, Warner-Lambert again declared that the '479 patent "claims a method of treating neurodegenerative diseases." (A.R., tab 11.) The company confirmed this representation in a November 1998 declaration, which listed the '479 patent as a method of use patent "to treat neurodegenerative diseases." (A.R., tab 13.) Warner-Lambert repeated this exact description of the scope of that patent when it provided "time sensitive patent information" about Neurontin® to the agency in April 2000. (A.R., tab 22.)

These statements are clear. Whenever it was called upon to describe the coverage of the '479 patent, Warner-Lambert (the patent owner to whose characterization the FDA has repeatedly said it defers) explicitly stated that the patent at issue covers the use of gabapentin to treat neurodegenerative diseases. The company never represented that the '479 patent covers the treatment of epilepsy. There is thus no real conflict between Warner-Lambert and Purepac as to the scope of that patent. Both companies have asserted that the only use claimed by the '479 patent is the treatment of neurodegenerative diseases, which of course is an off-label use. As such, the agency's policy arguments regarding the negative consequences that would occur if generic applicants were unilaterally able to disregard the NDA holder's construction of the patent are simply beside the point. Far from disregarding Warner-Lambert's statements as to the use claimed by the '479 patent, Purepac's section viii statement in fact accepts those statements at face value and relies on them in declining to file a

paragraph IV certification.[22/] Accordingly, the FDA's position that both the agency and Purepac were "bound to accept Warner-Lambert's characterization of the scope of the patent" (Def.'s Opp. at 32) actually bolsters plaintiff's claim that a paragraph IV certification was not necessary here.[23/]

In this light, not only are the FDA's policy arguments unhelpful, but countervailing policy considerations mitigate against the agency's position in this case. As suggested above, whenever generic applicants are compelled to use paragraph IV certifications, NDA holders obtain significant economic benefits. The most important of these are mandatory notice of the certification and the corresponding right to bring an immediate infringement action against the ANDA applicant under 35 U.S.C. § 271(e)(2)(A), which triggers the automatic 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii). This mechanism slows the process of bringing generic drugs to market, thus assuring

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[22/] The nature of Warner-Lambert's statements also distinguish this case from *Mylan Pharmaceuticals*, on which both the FDA and TorPharm rely. There, without actually deciding the issue, Judge Urbina agreed that in the case of a conflict between a pioneer and a generic applicant over the scope of a use patent's coverage, it is proper for the FDA to accept the judgment of the former. *See* 139 F. Supp.2d at 18 n.14. In that case, however, the NDA holder "submitted a statement to the FDA to the effect that the [patent at issue] covers all approved uses for [the drug at issue]." *Id*. Here, by contrast, Warner-Lambert's declarations make no comparably sweeping representation about the scope of the '479 patent, and thus do not conflict with Purepac's understanding of the use claimed by that patent.

[23/] Interestingly, TorPharm, in its brief and oral argument to the Federal Circuit in the infringement case brought against it by Warner-Lambert over the '479 patent, indicated its agreement with this claim. Describing the certification requirements that the Hatch-Waxman Amendments impose on ANDA applicants, TorPharm wrote that "[f]or a method-of-use patent that, *as in this case*, does not claim a use for which the applicant is seeking approval, the ANDA applicant must submit a statement that the applicant is not seeking approval for such use [*i.e*. a section viii statement]." (Pl.'s Reply, attach. B (Br. for Defs.-Appellees, at 5 (Apr. 29, 2002), *Warner-Lambert Co. v. Apotex Corp.*, No. 02-1073 (Fed. Cir.) (emphasis added)).) Thus, TorPharm's position in that litigation, which of course is diametrically at odds with its position before this Court, was that the '479 patent did *not* claim the use of treating epilepsy with gabapentin, and therefore that an ANDA applicant should have been required to submit a section viii statement as to that patent, not a paragraph IV certification.

the brand manufacturer of a continued monopolistic position in the market. If used in circumstances not intended by Congress, paragraph IV thus could upset the careful balancing of the rights of NDA holders and the interests of generic manufacturers (and the drug-buying public) that lies at the core of the Hatch-Waxman Amendments. *Cf. Abbot Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) ("Facing the classic question of the appropriate trade-off between greater incentives for the invention of new products and greater affordability of those products, Congress struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers.").

Indeed, this is why the statute allows ANDA applicants to use the section viii escape-hatch (with no mandatory notice and no automatic 30-month stay) in situations where there is no overlap between the uses claimed by the patents protecting the brand drug and the uses for which the generic manufacturer wishes to obtain approval. And, in this case, Warner-Lambert (the NDA holder) has done nothing to indicate any convergence between the scope of its method of use patent and the use for which the generic manufacturer seeks to market its drug product. Accordingly, to accept the FDA's position in this factually unusual (if not unique) case would result a substantial windfall to the NDA holder that cannot be squared with congressional intent. It would allow such firms to use non-existent (and never-asserted) patent rights in order to delay approval of ANDAs, thereby depriving the public of the benefit of low-cost drug products. *Cf. Allergan, Inc. v. Alcon Laboratories, Inc.*, 200 F. Supp.2d 1219, 1230 (C.D. Cal. 2002) ("Infringement actions under Section 271(e)(2) must . . . be limited to the Controlling Use Patents. An ANDA which seeks approval only for indications that are not claimed in a patent does not violate Section 271(e)(2).").

Aware that Warner-Lambert's statements as to the coverage of the '479 patent undermine the rationality of its decision to deny Purepac's ANDAs, the agency attempts to blur the clarity of those

statements by focusing on the context in which they were made and the regulatory consequences of making them. It can be assumed that Warner-Lambert filed its patent declarations knowing that the FDA would publish the referenced patents (including the '479 patent) in the Orange Book. And indeed, the '479 patent was ultimately listed in that publication, where it still remains. For these reasons, the FDA contends, the '479 patent must claim the use of treating epilepsy. The linchpin of this argument is the agency regulation that tells applicants for and holders of NDAs that the only method of use patents that may be included in the Orange Book are those that claim *approved* uses of approved drugs. *See* 21 C.F.R. § 355.53(b). Thus, according to the FDA, the only explanation for Warner-Lambert's decision to submit the '479 patent for publication (and never to seek its removal), is that the patent must claim an FDA approved use of gabapentin. And, of course, the only approved use of that drug is the treatment of epilepsy. Therefore, this syllogism concludes, the '479 patent claims the use of treating epilepsy, which makes a paragraph IV certification necessary. (Def.'s Opp. at 31.)

Defendant presents this argument in two ways. The first is a legal argument about the operation of section viii. The FDA has defended its refusal of Purepac's ANDAs on the grounds that section viii statements may not be used when a drug (like gabapentin) has only one approved use. This conclusion, the agency contends, is not some novel interpretation of that provision, but rather the inexorable result of the statute's logic. This logic runs as follows. Section viii statements are allowed only where the generic applicant seeks approval for a use not claimed by the patent.

> However, because the only method of use patents that properly may be listed in the Orange Book are those that claim an "approved" use of the listed drug, it follows inevitably that, when a drug has only a single approved use, any listed patent must necessarily claim that use, and any ANDA applicant seeking approval for that drug cannot, as a matter of fact or law, submit a valid section viii statement purporting to seek approval for a use not claimed by the patent.

(Def.'s Opp. at 23.)

This version of the argument fails, however, for its premise is fictitious. At bottom, the FDA regulations categorizing the types of patents that are to be listed in the Orange Book are hortatory, not definitional. That is, they do no more than tell patent owners what patents they may lawfully submit for publication. Thus, while the regulations tell those parties what they are *supposed* to do, they do not actually keep non-conforming patents, submitted in violation of the rules, out of the Orange Book. And herein lies the main flaw in the FDA's reasoning. It simply does not follow from the existence of a policy formally precluding patents claiming unapproved uses from appearing in the Orange Book that every patent in the Orange Book therefore necessarily claims an approved use.

The agency's argument about the operation of section viii thus represents the triumph of hope over reality. For, while it is true that the provision would work just as the FDA suggests *if the Orange Book in fact only contained patents claiming approved uses*, it is simply misguided to suggest that this situation must actually exist merely because it is supposed to exist. A utopian rule does not automatically create a utopia. As such, defendants' theory makes sense only if it were impossible for a brand manufacturer to break the agency's rules. But this assumption is belied by the FDA's own approach to policing Orange Book submissions. Indeed, the agency's much-touted "purely ministerial" role in the publication process, along with its policy of deferring to the representations of NDA holders about the scope of their patents, make it entirely possible that a brand manufacturer could submit a patent for publication (and see it published) without believing or averring that it actually covered an approved use. *Cf. aaiPharm*, 296 F.3d at 236 (describing how NDA holders can abuse the Orange Book listing process in the absence of any serious agency enforcement mechanism).

Accordingly, the FDA's argument here is, ultimately, an impermissible attempt to substitute what *should be* in the Orange Book for what *is* in the Orange Book. The agency has tried to construct a legal fiction about the scope of the '479 patent and to use that construct to ignore crucial facts (*i.e.* what Warner-Lambert actually said) about that patent's reach, facts that reveal the ultimate falsity of the agency's fiction. Because this effort finds no support in law (section viii and the FDA regulations implementing it speak only in terms of the uses actually *claimed* or *covered* by the patent, not whether the patent has been published in the Orange Book) or logic, it must be rejected. *See, e.g.*, *Allergan*, 200 F. Supp.2d at 1230 & n.9 (holding that paragraph IV certification was not required where generic applicant sought approval for only one indication of an approved drug, even though the patent in question – which claimed a non-approved use – had been listed, improperly, in the Orange Book).

The agency also presents this argument as a factual claim about Warner-Lambert's actual patent submissions regarding the '479 patent. This claim is that those statements must be read in light of the requirement barring NDA holders from submitting patents that claim unapproved uses to the agency for publication. Because it was undoubtedly aware of this rule, the FDA suggests, Warner-Lambert's decision to submit information about that patent must have reflected the company's belief that the '479 patent covered the approved use of gabapentin. In support of this claim, the FDA points to Warner-Lambert's November 1998 declaration. There, immediately below the certification that the '479 patent protects the use of treating neurodegenerative diseases, the company declared that the '544 patent, the '476 patent and the '479 patent "cover the composition, formulation, and/or method of use of Neurontin®." (A.R., tab 13.) Similarly, in its April 2000 submission, Warner-Lambert stated

that the '479 patent "covers a method of use of Neurontin®."[24/] (A.R., tab 22.) The FDA contends that these statements about "the" use of gabapentin must refer to the *approved* use of the drug -- to treat epilepsy. (Def.'s Opp. at 27 n.13.)

The Court is not persuaded. At the outset, what is most obvious about Warner-Lambert's statements is that they do not assert that the '479 patent covers the use of gabapentin to treat epilepsy. Nor, in either declaration, does the company identify the use claimed by the '479 patent as the approved use of gabapentin. On their face, then, the declarations simply do not say what the FDA wants them to say. The agency counters, that the declarations nevertheless imply what they are perhaps too coy to state explicitly. As such, the question becomes whether it was reasonable for the agency to infer from these rather opaque statements that Warner-Lambert intended to claim for the '479 patent the use of treating epilepsy.

For two reasons, the answer is no. First, the FDA's suggestion that the company made such a claim by implication is largely refuted by the explicit assertion, in the same documents, that the '479 patent covers a different use altogether. In light of these assertions, reading the sentence, "the '479 patent covers a use of Neurontin®" (or its counterpart in the 1998 declaration) as defendants would like – to mean that the patent covers the use of treating epilepsy – causes Warner-Lambert's submissions to become internally inconsistent, if not incomprehensible. To make matters worse, after unnecessarily creating this conflict through its artificial interpretation, the agency then chose to resolve it illogically, by favoring an unstated and ambiguous implication over a stated and definite declaration.

[24/] The form of these declarations follows the requirements that the FDA has imposed by regulation. *See* 21 C.F.R. § 314.53(c)(2)(i).

This is unreasonable. The FDA cannot profess allegiance to the Warner-Lambert's descriptions of its patents only to disregard unambiguous patent descriptions submitted by that company because it finds them inconsistent with the agency's contrived construction of those declarations.[25/]

Second, the FDA's own actions in response to Warner-Lambert's submissions belie the very inference the agency has now attempted to draw from them. After receiving those submissions, the FDA created use codes for the patents described therein. As explained above, these codes are used by generic applicants to determine the coverage of listed patents when they address those patents in their ANDAs. Based on Warner-Lambert's representations, the code that the agency assigned to the '479 patent is U-258, which corresponds to "treatment of neurodegenerative diseases." (A.R., tab 39.) Thus, while the FDA gave the '544 patent a use code for "treatment of epilepsy," the agency did not use that code for the '479 patent. The only plausible way of explaining this decision is that the FDA believed – and understood Warner-Lambert to believe – that the '479 patent covered the treatment of neurodegenerative diseases. In other words, when it generated and published its use codes, the agency followed the clear statements made by the NDA holder about the coverage of the '479 patent, and read no ambiguity or contrary meaning into the declaration that followed.

[25/] Moreover, Warner-Lambert has recently confirmed that the FDA's reading of the company's declarations was not merely strained, but incorrect. On December 13, 2002, Pfizer (on behalf of Warner-Lambert) faxed a letter to the Court, in an attempt to "provide additional information to clarify the meaning of Warner-Lambert's listings [of the '479 patent] to the benefit of all parties." In this letter, the company affirmed that its submissions concerning that patent "made no assertion with respect to any approved use. . . . At no time did Warner-Lambert represent to the FDA that the '479 listing covered the approved use for epilepsy nor was Warner-Lambert's listing otherwise intended to convey any such assertion." The NDA holder has thus reiterated what should have been obvious to the agency: that Warner-Lambert's patent listings represented only that the '479 patent claimed the use of treating neurodegenerative diseases, and did not suggest that the patent covered the treatment of epilepsy.

Having taken Warner-Lambert's statements about the scope of that patent at face value, and having therefore listed an unapproved use in the Orange Book, the FDA may not, consistent with the requirement of reasoned decisionmaking, impose a requirement on Purepac wholly incompatible with the agency's own understanding of the facts.[26/] Indeed, the agency has offered no justification for retreating from its previous position that the '479 patent covers only the treatment of neurodegenerative diseases.

Therefore, in light of Warner-Lambert's representations (the unambiguous meaning of which has now been confirmed by the company), and as reflected by the use codes assigned by the agency, the FDA's determination that the '479 patent claims the use of treating epilepsy "runs counter to the evidence before the agency," and is thus arbitrary and capricious. *Sinclair Broad. Group, Inc. v. FCC*, 284 F.3d 148, 159 (D.C. Cir. 2002) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *see also Ctr. for Auto Safety v. Fed. Highway Admin.*, 956 F.2d 309, 314 (D.C. Cir. 1992) ("An agency action is arbitrary and capricious if it rests upon a factual premise that is unsupported by substantial evidence."). Accordingly, when it rejected Purepac's attempted use of a section viii statement regarding that patent, the FDA committed a "clear error in

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[26/] Indeed, the FDA seems to have recognized in a recent case the importance of use codes in determining how an ANDA applicant should address the patents submitted by the NDA holder. In *Dr. Reddy's Laboratories, Inc. v. Thompson*, a generic manufacturer (Dr. Reddy) specifically excluded from its proposed labeling the uses of the drug asserted by the use codes for the patent in question. In its oral presentation to the court, the FDA argued that under those circumstances, the applicant was not "claiming a use covered by the patent," and therefore that a paragraph IV certification was not required. Hr'g Tr., Civ. Act. No. 02-452 (D.N.J. Sept. 13, 2002). Just like Dr. Reddy, Purepac's proposed labeling excluded the use asserted by the use code for the patent in question (the '479 patent). Accordingly, the sensible approach advocated by the agency in *Dr. Reddy's* vindicates plaintiff's position here.

judgment." *AT&T Corp. v. FCC*, 236 F.3d 729, 734 (D.C. Cir. 2001) (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974)).

Despite this determination, however, the Court will not grant Purepac's request to enjoin the FDA from approving TorPharm's application because it contains a paragraph IV certification as to that patent. To this end, plaintiff has argued that the Court should fashion its injunctive relief "to protect Purepac's exclusivity interest by compelling intervenor TorPharm to withdraw its Paragraph IV certification against the '479 patent."[27/] (Pl.'s Opp. at 4.) The basis for plaintiff's argument is its belief that paragraph IV certifications and section viii statements are mutually exclusive alternatives. Therefore, if one is proper, the other could not be as a matter of law.

It is true that the FDA has previously suggested as much (Def.'s Opp. 21 n.9), and has specifically stated that "an applicant does not have the option of making a certification under [paragraph IV] in lieu of, or in addition to, a statement under [section viii]." *ANDA Rulemaking*, 59 Fed. Reg. at 53,347. However, at oral argument the agency stated that it has not taken a definitive position as to whether equitable considerations might ultimately persuade it to allow two applicants to submit a certification and a statement, respectively, with respect to the same patent. As such, the FDA has not decided whether it could, or would, approve TorPharm's application with a paragraph IV certification to the '479 patent even if the Court were to direct the agency to accept Purepac's application with a

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[27/] Purepac's concern here is obvious. If TorPharm's application is approved with the paragraph IV certification in place, TorPharm would be the first generic manufacturer to have filed a successful ANDA with such a certification as to the '479 patent. As such, it would be entitled to a 180-day exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv), which would force Purepac to share the exclusivity to which it is entitled by virtue of being the first applicant to file a paragraph IV certification as to the '482 patent.

section viii statement. Because the agency has not done so, and because Purepac has not demonstrated that such a result is barred by the terms of the statute or precluded by existing FDA regulations, the Court will leave this delicate question for the agency to resolve in the first instance.

The Court's power to issue "programmatic relief" clearly does not compel it to decide such an issue before the agency has had a chance to act.[28/] It is a far more sensible course for the Court to offer the FDA the opportunity to sort out the considerable complexities associated with the potentially competing exclusivity periods to which Purepac and TorPharm may be entitled, instead of enjoining agency action that has not even happened.

CONCLUSION

In sum, the FDA's decision not to approve Purepac's ANDAs because they contained section viii statements regarding the '479 patent, impermissibly disregarded both Warner-Lambert's and the agency's own understanding of the coverage claimed by that patent. That decision is thus factually unsupportable and irreconcilable with the language and intent of the FDCA. For these reasons, it violates the APA. Moreover, Purepac's suit is not barred by the doctrine of laches. Accordingly, the Court will enter final judgment on plaintiff's behalf, and vacate the FDA's determination that ANDAs to market gabapentin for the treatment of epilepsy cannot be approved because they do not include

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[28/] In this regard, plaintiff's reliance on *National Mining Ass'n v. U.S. Army Corps of Engineers*,145 F.3d 1399, 1409-10 (D.C. Cir. 1998), as authority for the granting of such relief is clearly misguided. That case stands for the proposition that a nationwide injunction invalidating an agency rule of broad applicability is appropriate even where a single plaintiff has challenged the legality of the rule. The present case, in sharp contrast, involves not a challenge to a broad FDA rule, but instead a highly fact-specific challenge to a particular agency decision that affects only the limited class of parties seeking approval to market generic versions of a gabapentin. As such, the relief granted by the Court is appropriately limited to the unique factual circumstances presented here.

paragraph IV certifications regarding the '479 patent. However, the Court will not bar the FDA from considering TorParm's ANDA with such a certification in place.

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ELLEN SEGAL HUVELLE
United States District Judge

DATE: January 6, 2003